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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,633	01/10/2002	Akio Kobayashi	111632	6574

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EXAMINER	
SHAY, DAVID M	
ART UNIT	**PAPER NUMBER**
3735	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/041,633	KOBAYASHI	
	Examiner	Art Unit	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 19, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-10,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-10,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *June 19, 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant has filed a substitute specification and asserts that the substitute specification filed June 19, 2006 conforms to 37 CFR 1.25(c) because "it is submitted with markings showing all changes relative to the immediate prior version of the specification on record, i.e. the amendments to the specification included with the October 2, 2002 Petition and Preliminary Amendment." However, a review of the record reveals that the amendment filed October 2, 2002 was an amendment to the drawings, and no specification amendment is of record, either with the aforementioned filing or any other filing to date. Thus the substitute specification filed June 19, 2006 is NOT in compliance with 1.125(c) and as such has NOT been entered.

Applicant argues that there is no requirement to label the drawings with indicia indicating what the elements therein are. This argument is clearly erroneous in view of rule 1.83 (a).

With regard to the art rejection, applicant acknowledges that Abela et al ('982) teaches the use of a hollow optical fiber to deliver genetic material to cells. This is done by porating the cell: incising the cell membrane to allow the passage of the genes into the interior portion thereof. Applicant argues that Matsuura et al (1998) do not teach irradiating a living cell. However, since Abela et al ('982) already teaches this, it is not necessary for Matsuura et al (1998), which teaches medical applications, generally, to do so as well. With regard to the Lewis et al reference, applicant argues that Lewis et al is directed to providing precise cuts in tissue, for reasons that are unclear to the examiner, applicant appears to conclude the since the tapered tip of Lewis et al is used for providing precise cuts to tissue, that there is no motivation to combine the teaching with that of Abela et al ('982), which requires precise cuts in the tissue of the cell walls. However, since the precise portions of the cell walls which are ablated in Abela et al ('982) would be more precisely ablated by using the tapered tips of Lewis et al, thereby allowing

more cells to remain viable and express the genotypes intended to be transferred to the cells in Abela et al ('982), this appears to the examiner to be a motivation to person having ordinary skill in the art to make the combination, rather than a deterrent.

The drawings are objected to because the elements of Figure 2 are not **labeled** with indicia indicative of their function. Rule 1.83(a) requires features of the drawing to be "illustrated in the drawing in the form of a graphical symbol or a **labeled** representation." Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "laser beam with 1-100 mJ/cm^2 of energy density and 1-1000mJ/cm^2 of the energy output"; the "irradiating the cell through the

surface of the quartz glass chip coated with metal"; "passing the laser beam through the surface of the quartz glass chip coated with metal"; "introducing foreign matter"; and "passing the laser gear through an inert gas" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The specification is objected to as containing grammatical errors, and additionally because the Table on page 12 is inconsistent with itself (for example a 17.7% increase from 3.92 would be 3.92 + 3.92 (.177) = 4.61, not 6.97, as set forth in the table) and must be corrected, no new matter should be added.

The amendment filed June 19, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "laser beam with 1-100 mJ/cm^2 of energy density and 1-1000mJ/cm^2 of the energy output"; the "irradiating the cell through the surface of the quartz glass chip coated with metal"; "passing the laser beam through the surface of the quartz glass chip coated with metal"; "introducing foreign matter"; and "passing the laser gear through an inert gas".

Applicant is required to cancel the new matter in the reply to this Office Action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 5-10, 13, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure and the disclosure or amended is silent on "laser beam with 1-100 mJ/cm^2 of energy density and 1-1000mJ/cm^2 of the energy output"; the "irradiating the cell through the surface of the quartz glass chip coated with metal"; "passing the laser beam through the surface of the quartz glass chip coated with metal"; "introducing foreign matter"; and "passing the laser gear through an inert gas" has not been enablingly described in the specification either as to the manner in which the laser is transmitted through the surface of

an element coated with metal, or the manner in which the laser gear is passed through the inert gas".

Claims 2, 5-10, 13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite as it appears to fail to further limit the claim from which it depends, as it is unclear how the particular wavelength used manipulatively affects any of the claimed steps, and therefore what further limitation is intended to be implied is unclear. Claims 5, 6, and 14 are indefinite as they appear to fail to further limit the claim from which they depend, as it is unclear how the composition of the coating on the glass chip or optical fiber manipulatively affects any of the claimed steps, and therefore what further limitation is intended to be implied is unclear and are further unclear as it is not understood how the beam will be transmitted through the surface which is coated with metal. Claim 7 is indefinite as it appears to fail to further limit the claim from which it depends, as it is unclear how the particular laser employed manipulatively affects any of the claimed steps, and therefore what further limitation is intended to be implied is unclear. Claims 9 and 10 are indefinite as they appear to fail to further limit the claim from which they depend, as it is unclear how the particular material to be introduced manipulatively affects any of the claimed steps, and therefore what further limitation is intended to be implied is unclear. Claim 13 is indefinite as it appears to fail to further limit the claim from which it depends, as it is unclear how the particular inert gas employed manipulatively affects any of the claimed steps, and therefore what further limitation is intended to be implied is unclear.

Claims 1, 2, 5-10, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abela et al ('982) in combination with Matsuura et al (1998) and Lewis et al. Abela et al ('982) teach the method as claimed except for the specific recitation of the use of a hollow fiber, the specific laser energies, or the quartz chip (please note that the absence of the quartz chip implies the absence of other structures predicated thereon, such as the hydroxide groups). Matsuura et al (1998) teaches forming hollow waveguides for the delivery of excimer laser light from hollow fibers that are coated with aluminum and are filled with an inert gas. Lewis et al teaches the desirability of using a wave guiding device with a tapered tip in a medical system and method for applying high energy radiation. It would have been obvious to the artisan of ordinary skill to employ a device and method as taught by Abela et al ('982) in the device and method of Matsuura et al (1998) since Matsuura et al (1998) specifically discloses the desirability of using hollow waveguides in medical applications; or to use the device and method of Matsuura et al (1998) in the device and method of Abela et al ('982), since Abela et al ('982) disclose no particular fibers and since these fibers efficiently transmit high energy radiation while exhibiting favorable bending radii; and in either case to employ the tapered tip of Lewis et al, since this provides beam sizes in the range required by Abela et al ('982); or to employ the tapered tip of Lewis et al on the waveguide of Abela et al ('982), since this provides beam sizes in the range required by Abela et al ('982), or to employ the device and method of Abela et al ('982) in the device and method of Lewis et al, since Lewis et al disclose drilling through cell walls as a preferred use of the device, and in either case to employ the hollow waveguide of Matsuura et al (1998), since this allows for the transmission of greater energies and avoids the formation of color centers, which is a problem, as taught by Lewis et al; or to provide the method and device

of Lewis et al in the method and device of Matsuura et al (1998), since the tapered tip of Lewis et al provides greater energies and or to provide the method and hollow waveguide device of Matsuura et al (1998) in the device and method of Lewis et al, since this would avoid the production of color centers and enable larger energies to be delivered, and in either case to employ the method and device of Abela et al since this is a medical method as suggested by Matsuura et al (1998), which would benefit from the delivery of high energy radiation and since this device and method is useful for drilling into cell walls, as taught by Lewis et al; and in any case, to employ a laser outputting power in the range claimed, since this is necessary to enable the production of the claimed power output by the fiber, is not critical and provides no unexpected result; to employ a chip as claimed, since this condenses the light and is commercially available, as taught at paragraph [0051] of the instant disclosure; to use any of the claimed inert gasses, since these are all well known inert gasses in the art, are not critical and provide no unexpected result, thus producing a method such as claimed.

Applicant's arguments filed June 19, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

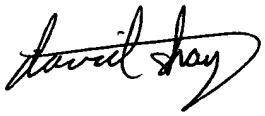
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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